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Editorial Comment

Catheter-Based Intervention: Pushing the Envelope*

TONY M. CHOU, MD, FACC

San Francisco, California

The 20th anniversary of the first human application of percutaneous transluminal coronary angioplasty (PTCA) was celebrated in 1997 (1). During this brief lifetime, catheter-based revascularization has seen tremendous growth, expanding indications and dramatic technologic improvements. PTCA is now accepted as an effective therapy, with hundreds of thousands of procedures performed annually in the United States alone. However, timely, objective comparisons of PTCA, bypass surgery and medical therapy as options for patients with coronary artery disease have been limited. Although randomized trials have demonstrated that PTCA has a role in relieving anginal symptoms (2), is comparable to operation for multivessel disease in selected patients (3,4) and can serve to provide effective reperfusion in the setting of acute myocardial infarction (5–7), such important clinical data often reach publication when advancing technologies have made their relevance to modern practice unclear. Data on new devices are often from single-center, single-device reports that cannot agree on outcomes, such as "success" and "restenosis," making comparisons problematic. Thus, patient selection and appropriate technique application for percutaneous coronary revascularization remains a case by case challenge.

Registry data have been key elements in the field of interventional cardiology in the documentation of strategy and outcome. The National Heart, Lung, and Blood Institute (NHLBI) has sponsored three important multicenter data collection efforts: PTCA I (1977 to 1981, 3,000 patients); PTCA II (1985 to 1986, 2,431 patients); and the New Approaches to Coronary Intervention (NACI) registry (1990 to 1994, 4,389 patients). Patients selected for PTCA in the PTCA II versus PTCA I registry demonstrated a clear trend: increased age, higher likelihood of multivessel disease, poorer left ventricular function, higher rate of previous myocardial infarction and increased lesion complexity (8). Nevertheless, with the advances in balloon and angioplasty techniques, most notably the development of steerable guide wires and improvements in balloon catheter technology (the over the wire system, lower balloon profiles, improved trackability, perfusion systems), PTCA results appeared to continue to maintain high acute success rates despite increasing lesion complexity and patient comorbidity. A recent comparison of PTCA data from women in the PTCA II registry with a 500-woman component of the NHLBI NACI registry from 1993 to 1994 confirmed the improving clinical success rates of PTCA despite the higher risk profile (9).

The PTCA registries were critical in establishing and validating the American College of Cardiology/American Heart Association (ACC/AHA) scoring system, which allowed systematic characterization of stenoses for catheter-based approaches (10,11). The limitations of balloon angioplasty were evident from these data, and the development of dozens of new technologies followed.

In this issue of the Journal, the comparison by King et al. (12) of the PTCA II and NACI registries continues the previous trends. Importantly, this comparative study found no superiority of the newer devices over PTCA when adjusted for an elective setting and the overall higher level of illness in the NACI cohort (12). Patient survival and freedom from target lesion revascularization by catheter or surgeon were the same in the two settings. It is a clinically important observation that the onset of new technologies has allowed for treatment of older patients with a higher rate of comorbidity, heart failure, previous myocardial infarction and previous bypass while maintaining a success rate similar to that of the PTCA II database (12).

How does the NACI registry translate to today's practice? Even in the few years since the NACI registry ended enrollment, the practice of interventional cardiology has evolved dramatically. The limitations of comparing registries from differing time frames make direct application to today's practice difficult. Although the precise data are not known, there has been a dramatic increase in the use of new single-device procedures, such as rotational atherectomy (11.5% of NACI registry patients examined), stenting (9.2%) and multiple-device procedures (6.6%). The use of directional coronary atherectomy (DCA) (30.6% of NACI patients examined) has gone down significantly since the long-term results of the randomized PTCA versus DCA trials were described (13,14).

The present study (12) examined only patients who underwent revascularization with new devices in the NACI registry as part of a elective or planned strategy. The entire NACI registry included >4,000 patients, many of whom presented with rescue stent procedures and acute myocardial infarction and were not included in the present analysis. Despite the more complex presentation of the entire NACI registry, high procedural and lesion success rates were maintained (15). Much of this success must be attributable to the advance of catheter technologies. The use of stents in rescue situations—a practice that has clearly changed the aggressiveness of balloon angioplasty use as well as new devices—was exclusionary. One would have to think that the use of stents in rescue situations would affect direct comparisons of the technology. Given that

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From the Adult Cardiac Catheterization Laboratories, Division of Cardiology and Cardiovascular Research Institute, University of California San Francisco, San Francisco, California.

Address for correspondence: Dr. Tony M. Chou, Adult Cardiac Catheterization Laboratories, Box 0124, University of California San Francisco, San Francisco, California 94143-0124. E-mail: chou@cardio.ucsf.edu.

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Abbreviations and Acronyms

DCA = directional coronary atherectomy
NACI = New Approaches to Coronary Intervention
NHLBI = National Heart, Lung, and Blood Institute
PTCA = percutaneous transluminal coronary angioplasty

the advent of stenting allows more aggressive balloon sizing and dilation, the practice of PTCA during the NACI registry era is different from the use of PTCA during the PTCA II registry. This unavoidable confounder is further complicated by the relatively ubiquitous use of stenting today.

Many centers report rates of stenting in catheter-based intervention of 70% to 80%—a dramatic difference from the NACI cohort. Additionally, the NACI stent data were collected during an age of routine use of anticoagulation rather than antiplatelet therapy. During the early 1990s, the use of higher pressure stent deployment and intravascular ultrasound—techniques that appear to have an impact on overall success rates—were not common. Clearly, stenting today is safer and has a sustained improved outcome in combination with current techniques and antiplatelet therapy (16–19). With the release of newer stents with improved delivery characteristics, lower profiles and greater flexibility, the use of coronary stenting will increase as stent deployment approaches the ease of simple balloon dilation.

The NACI data predated the use of new adjuvant therapies that appear to be improving the acute and long-term results of catheter-based techniques. The focus on the platelet as a key agent in abrupt closure and restenosis (20,21), and the development of platelet glycoprotein IIb/IIIa inhibitors appears to be an area of great promise, as the experience with the monoclonal antibody fragment abciximab (22,23) and tirofiban (24) have borne out. The development of new antiplatelet agents will see our present-day management evolve. Local delivery of pharmacologic agents, including directed molecular therapies, will continue to be explored and may have a great impact (25–27). Catheter-based radiotherapy appears to improve short-term outcomes when used in conjunction with stenting in patients with restenosis (28).

The era of new devices in catheter-based revascularization has seen headway made in treating restenosis, diffuse disease, calcified lesions and reductions in abrupt closure. The lack of a clear benefit with the NACI database emphasizes the need for good clinical judgment in interventional decision making. This dynamic is vitally important to maintain the momentum that the "second-tier" devices have sustained since the approval of DCA in 1984. Procedures in complex lesions and high risk patients that could not have been feasible a decade ago are now considered routine. Unfortunately, randomized, controlled clinical trials evaluating these devices as they are released are logistically difficult, costly and obsolete by the time of completion because of rapid device evolution during the trial period. It is here that registry data are most valuable. Although interventional cardiologists push the frontiers of what and whom it is possible to treat by means of catheter-based approaches with the use of new devices, it is clear that there is much work to be done to improve the long-term results.

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